K020137

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MAR 4 2002

510(k) Summary

Contact: Grant Ramaley

Date Prepared: January 29, 2002

Trade or Proprietary Name: Aseptico Autoclavable Handpieces

Classification Name: Dental handpieces and accessories (872.4200)

Description of handpiece characteristics

Aseptico's autoclavable handpieces are intended to be used by dental professionals for a broad range of intra-oral dental procedures. These handpieces integrate requirements specified in International Standard ISO 7785-2 *"Dental handpieces - Part 2: Straight and geared angle handpieces"*. This standard describes in precise detail how dental handpieces are typically designed and should perform, including withstanding a minimum of 250 cycles of steam autoclaving.

Aseptico's autoclavable dental handpieces vary from one model to another in three fundamental ways: They have different gear ratios, different methods for attaching burs and files (latch or push button style), and may be either straight or angled. The most common and notable variation between Aseptico's handpieces are their gear ratios. Different handpiece ratios convert the same input rotational force of an electric micro-motor into different bur speeds and bur torque. Aseptico's handpieces use a different arrangement of geared components to obtain different ratios of input to output speeds. These ratios are represented by numbers ranging from 1:1 (no reduction) to a 256:1 reduction.

All Aseptico's dental handpieces are tested and validated by a third party laboratory to a sterility assurance level (SAL) of 10^{-6}. Every handpiece is designed to ensure that the inner-most, hardest to reach parts of the handpieces are sterile when following sterilization procedure included in the instructions for use.

Aseptico's fully autoclavable handpieces are used for a wide range of dental procedure including;

1) Dental endodontic surgeries, such as drilling into the root canal,
2) General dentistry, such as removing carious material from the dentine.
3) Performing dental implant surgeries, such as perforating the bone, and tapping and threading procedures required before placement of implant prosthetics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

Mr. Grant Ramaley
Quality Regulatory Affairs Manager
Aseptico, Incorporated
8333 216th Street S.E.
Woodinville, Washington 98072

Re: K020137
Trade/Device Name: Aspectico Autoclavable Handpieces
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: January 11, 2002
Received: January 16, 2002

Dear Mr. Ramaley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020137

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510(k) Number (if known) K020137

Device Name: Dental Handpieces and Accessories

Indications For Use:

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3) Performing dental implant surgeries, such as perforating the bone, and tapping and threading procedures required before placement of implant prosthetics.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020137

Prescription Use ✓ OR Over-The-Countern Use____
(Per CFR 801.109)

(Optional Format 1-2-96)